

**EPA REGISTRATION NUMBER 43813-57 – VOL 2**



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

December 28, 2015

William R. Goodwine  
Director  
WW Regulatory Affairs & Risk Assessment  
Janssen PMP, Janssen Pharmaceutica NV  
1125 Trenton-Harbourton Road  
Titusville, NJ 08560-0200

Subject: Non-PRIA (Pesticide Registration Improvement Act) Formulation Amendment –  
Updating Manufacturing Sites for the Basic Confidential Statement of Formula (CSF)  
Product Name: FYSIUM  
EPA Registration Number: 43813-57  
Application Date: December 23, 2015  
OPP Decision Number: 509992

Dear Mr. Goodwine:

The CSF referred to above, submitted in connection with registration under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, is acceptable. This approval does not affect any terms or conditions that were previously imposed on this registration. You continue to be subject to existing terms or conditions on your registration and any deadlines connected with them.

Please note that the record for this product currently contains the following acceptable CSF:

- Basic CSF dated 12/16/2015

Any CSFs other than those listed above are superseded/no longer valid.

If you have any questions, please contact Andrew Reighart of my team by phone at (703) 347-0469 or via email at [reighart.andrew@epa.gov](mailto:reighart.andrew@epa.gov).

Sincerely,

A handwritten signature in black ink, appearing to read "For" followed by a stylized signature, is placed above the typed name.

Andrew C. Bryceland, Team Leader  
Biochemical Pesticides Branch  
Biopesticides and Pollution  
Prevention Division (7511P)  
Office of Pesticide Programs



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

September 1, 2015

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

JOANNE HAMAN-HOY  
JANSSEN PMP  
JANSSEN PHARMACEUTICA NV  
1125 TRENTON-HARBOURTON RD  
TITUSVILLE, NJ 08560-0200

PRODUCT NAME: FYSIUM  
COMPANY NAME: JANSSEN PMP  
OPP IDENTIFICATION NUMBER:  
EPA FILE SYMBOL: 43813-57  
EPA RECEIPT DATE: 08/26/15

SUBJECT: RECEIPT OF AMENDMENT

DEAR REGISTRANT:

The Office of Pesticide Programs has received your application for an amendment and it has passed an administrative screen for completeness.

During the initial screen we determined that the application appears to qualify for fast track review. The package will now be forwarded to the Product Manager for review to determine its acceptability for fast track status.

If you have any questions, please contact Biologicals & Pollution Prevention Division, PM Team 91, at (703) 305-6928.

Sincerely,

A handwritten signature in black ink, appearing to be "J. [unclear]".

Front End Processing Staff  
Information Services Branch  
Information Technology & Resources Management Division



United States  
Environmental Protection Agency  
Washington, DC 20460

☒ Registration  
☐ Amendment  
☐ Other

OPP Identifier Number

## Application for Pesticide - Section I

1. Company/Product Number 43813-57	2. EPA Product Manager Linda Hollis	3. Proposed Classification <input checked="" type="checkbox"/> None <input type="checkbox"/> Restricted
4. Company/Product (Name) FYSIUM	PM# 90	
5. Name and Address of Applicant (Include ZIP Code) Janssen PMP, Division of Janssen Pharmaceutica NV 1125 Trenton-Harbourton Road Titusville NJ 08560-0200 <input type="checkbox"/> Check if this is a new address		6. Expedited Review. In accordance with FIFRA Section 3(c)(3) (b)(i), my product is similar or identical in composition and labeling to: EPA Reg. No. _____ Product Name _____

## Section - II

<input checked="" type="checkbox"/> Amendment - Explain below.	<input type="checkbox"/> Final printed labels in response to Agency letter dated _____
<input type="checkbox"/> Resubmission in response to Agency letter dated _____	<input type="checkbox"/> "Me Too" Application.
<input type="checkbox"/> Notification - Explain below.	<input type="checkbox"/> Other - Explain below.

Explanation: Use additional page(s) if necessary. (For section I and Section II.)

To amend Box 2 of the CSF to include additional production sites.

## Section - III

1. Material This Product Will Be Packaged In:				2. Type of Container	
Child-Resistant Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Unit Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Water Soluble Packaging <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		<input checked="" type="checkbox"/> Metal <input type="checkbox"/> Plastic <input type="checkbox"/> Glass <input type="checkbox"/> Paper <input type="checkbox"/> Other (Specify) _____	
* Certification must be submitted			If "Yes" Unit Packaging wgt.	No. per container	
			If "Yes" Package wgt	No. per container	
3. Location of Net Contents Information <input type="checkbox"/> Label <input checked="" type="checkbox"/> Container		4. Size(s) Retail Container 4.135 - 12.342 fl. oz. (122.3-365 mL)		5. Location of Label Directions <input checked="" type="checkbox"/> On cartridge	
6. Manner in Which Label is Affixed to Product <input checked="" type="checkbox"/> Lithograph <input type="checkbox"/> Paper glued <input type="checkbox"/> Stenciled			<input type="checkbox"/> Other _____		

## Section - IV

1. Contact Point (Complete items directly below for identification of individual to be contacted, if necessary, to process this application.)		
Name William R. Goodwine	Title Director, WW Reg. Affairs & Risk Assess.	Telephone No. (Include Area Code) 609/730-2607
<b>Certification</b> I certify that the statements I have made on this form and all attachments thereto are true, accurate and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.		6. Date Application Received (Stamped)
2. Signature <i>William R. Goodwine</i>	3. Title Director, WW Reg. Affairs & Risk Assess.	
4. Typed Name William R. Goodwine (bgoodwi@its.jnj.com)	5. Date December 23, 2015	

August 25, 2015

Document Processing Desk (AMEND)  
Office of Pesticide Programs (7504P)  
U.S. Environmental Protection Agency  
Room S-4900, One Potomac Yard  
2777 South Crystal Drive  
Arlington, VA 22202-4501

Re: FYSIUM (Reg. No. 43813-57)  
Application for Amended Registration

Attention: Andrew Bryceland  
Team Leader

Janssen PMP, a Division of Janssen Pharmaceutica NV is submitting the enclosed Confidential Statement of Formula to update Box 2 with FYSIUM manufacturing site changes.

The Confidential Statement of Formula we are updating is dated April 27, 2015 which is the most recent and current CSF on file with the Agency.

Please contact me if you have any questions related to this action.

Sincerely,



William R. Goodwine  
Director, WW Regulatory Affairs & Risk Assessment  
Preservation & Material Protection  
T: 609/730-2607 F: 609/730-2080 [bgoodwi@its.jnj.com](mailto:bgoodwi@its.jnj.com)

Enclosures

